



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0241]

Guidance for Industry on Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #188 entitled "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine." The purpose of this guidance is to assist sponsors or non-applicants with filling out Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report," in both paper and electronic format, as required by FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Margarita Brown, Center for Veterinary Medicine (HFV-241), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9048. [margarita.brown@fda.hhs.gov](mailto:margarita.brown@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 25, 2010 (75 FR 29352), FDA published the notice of availability for a draft guidance #188 entitled "Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine," giving interested persons until August 9, 2010, to comment on the draft guidance. FDA made changes to the draft document in response to these comments, to clarify the information that we expect to receive, to reflect ongoing International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) activities in which FDA is participating, and to provide direction for voluntary use of CVM internal terms for medication errors. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated May 24, 2010.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in section 512(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)) have been approved under 0910-0645.

### IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

### V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: October 18, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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